DETAILED ACTION

Response to Amendment

In the reply filed 7/13/10, applicant added claims 1, 8, and 10, and cancelled claims 2 and 9. Claims 1, 3-6, 8, 10-16, 18-21, 58, 60-75, and 78-83 are currently pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 1, 5, 6, 9-15, 17-21, 58, 60, 62, and 64-71, and 78-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rubenstein et al. (US 7,025,742) in view of Drevet et al. (US 5,643,195).

2. With respect to Claim 1, 5, 6, 9-15, 58, 60, 62, 64-67, and 78-83, Rubenstein et al. (hereafter 'Rubenstein') discloses a fluid shunt for regulating the flow of cerebrospinal fluid ("CSF"), said shunt comprising an inlet port 184, an outlet port 186, a fluid passageway between said inlet and outlet, and a valve 194 situated between the inlet and outlet. The valve defines a drain port between an upstream side and a downstream side of the fluid passageway. The valve comprises a mask having a cutout thereon that is alignable with the drain port. The device further comprises a piston 196 having a piston face defined on the upstream side of the passageway and being

displaceable to actuate the valve. The fluid bearing on the piston face will actuate the valve and allow fluid communication between the inlet and outlet ports. When the piston is activated by the presence of a threshold pressure, the cutout will be moved vertically so as to selectively allow fluid flow through the drain port (see Figure 17). The piston is displaceable along a vertical piston travel axis, and fluid flowing through the cutout valve between the upstream and downstream sides flows substantially perpendicular to said axis. When a sufficient pressure differential across the diaphragm is present, the diaphragm will displace the piston along the travel axis and open the valve. Further, because the valve is initially in the closed position, downstream pressure is substantially prevented from affecting the position of the piston (see Figure 16). Therefore, the position of the piston is independent of the pressure in the downstream side of the fluid passage.

Rubenstein teaches the device substantially as claimed, but does not specifically teach that the cutout is defined on the sidewall of the *piston*, nor does Rubenstein specifically teach that the biasing member is a deformable diaphragm.

Regarding the arrangement of the cutout, it has been held that the mere rearrangement of parts does not constitute a patentable improvement in the art when said rearrangement does not provide a non-obvious difference in functionality (MPEP § 2144.04). In this case, Rubenstein teaches a piston that is integral with a valve member, the valve member serving to *selectively block* fluid flow from the inlet to the outlet. The valve member 194 further comprises a cutout for allowing fluid to pass when the piston is disposed at a specific height (i.e. when a specific amount of pressure is

present within the chamber). However, it is the examiner's position that the specific vertical location of the cutout is irrelevant, *so long as it corresponds with the vertical position of the piston such that it selectively opens and closes in response to pressure differences*. Merely repositioning of the cutout from the wall from the sidewall of the valve to the sidewall of the piston would have been an obvious rearrangement of parts to one of ordinary skill in the art at the time of invention, because doing so would provide a pressure-responsive cutout valve that responds only to fluid pressure in the upstream portion of the device.

Regarding the deformable diaphragm, Drevet teaches a CSF shunt comprising a flow control member having an inlet port, an outlet port, a fluid passageway between said inlet and outlet, and a valve 14 situated between the inlet and outlet. The valve defines a drain port between an upstream side and a downstream side (6 and 13) of the fluid passageway. A piston is configured to selectively position the valve based on fluid pressure (see Abstract). The fluid bearing on the piston face will actuate the valve and allow fluid communication between the inlet and outlet ports. Specifically, a portion of the piston face is defined by a deformable diaphragm 9 that includes a fluid side 7 bounded by the upstream side 7 of the fluid passageway, and an opposite side isolated from the fluid passage. The deformable diaphragm is connected to a spring 17 such that the diaphragm and spring provide a biasing force to maintain the valve in a closed state unless a sufficient pressure differential is provided. When fluid pressure in the first chamber builds, the fluid will press against the diaphragm, thereby urging the piston downward. Once the fluid pressure against the piston reaches a threshold level, it will

overcome a biasing force provided by the biasing member, thereby displacing the valve and allowing fluid to flow. Once fluid pressure drops back below the threshold level, the biasing member will urge the piston upward, thereby closing the valve. Further, Drevet teaches that the pressure of the spring 17 is capable of being adjusted by means of a screw 18 (see Figure 1). This type of piston biasing system is well known in the art because it allows for precise pressure-based control over the position of the valve. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the flow control system of Rubenstein with Drevet's diaphragm-based piston biasing system in order to provide a well-known, alternate means for controlling fluid flow through the valve in response to upstream fluid pressure.

3. With respect to Claims 18, 20, 21, and 68-70, the device is designed to drain CSF from the cranium to a resorption site, such that the peritoneum.

4. With respect to Claim 19 and 71, the outlet portion 4 has an extended flexible catheter 5 extending therefrom.

5. Claims 3, 4, 16, 61, and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rubenstein in view of Drevet, and further in view of Drake et al. (US 5,192,265). Rubenstein and Drevet reasonably suggest a flow-regulating CSF shunt substantially as claimed (see rejection above), but do not specifically disclose that the diaphragm comprises a fluid side in contact with the upstream chamber and a gas side,

opposite the fluid side, bounded by a regulatable gas chamber. Drake discloses an adjustable CSF shunt comprising a fluid passageway 5 surrounded by a pair of flexible walls (i.e. diaphragms). A gas chamber 9 is disposed on the opposite side of the flexible sheets from the fluid passageway, such that pressure is applied to the diaphragms to form a valve (Figure 1). When a low pressure differential exists between the inlet and the outlet, the valve is closed. When a pressure differential between the inlet port 7 and outlet port 8 is present, however, the diaphragms will deform, allowing fluid to pass through the fluid passageway. Furthermore, Drake discloses that the gas pressure in the gas chamber 9 may be manually adjusted by moving a ball 14 through the gas pressure control means 10 (Column 3, Lines 34-44). The use of a gas source therefore allows a pressure to be applied to the opposite side of the diaphragm, thus eliminating the need for a spring member to apply pressure to the diaphragm. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the flow control device of Rubenstein and Drevet with the use of a gas source to apply pressure to the opposite side of the diaphragm in order to provide a well known, alternate means for controlling the pressure differential between the inlet and outlet of a CSF shunt.

Allowable Subject Matter

6. Claims 8 and 72-75 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

Regarding Claim 8, Rubenstein's cutout valve is not designed to completely close the flow path, but rather to control a non-zero rate at which fluid flows. Further, The prior art neither teaches nor suggests the use of a mask that is a substantially flexible membrane, such that the fluid pressure creates a seal as the piston presses against said mask. Rubenstein's piston is limited to bidirectional motion, and does not comprise a flexible member against which the piston presses. Furthermore, because the purpose of Rubenstein's device is not to stop fluid flow at a given time, there is no motivation to modify Rubenstein's device with a flexible mask that creates a fluid-tight seal. Doing so would destroy the functionality of Rubenstein's device because fluid flow could potentially be stopped at certain piston positions.

Regarding Claims 72-75, applicant's argument that one of ordinary skill in the art would not have modified Rubenstein and Drevet based on Zinger's disclosure have been found persuasive. The prior art does not teach or suggest a downstream-pressure-independent flow valve that has a cutout piston with a rotary axis of rotation.

Response to Arguments

Applicant's arguments filed 7/13/10 with respect to the combination of Rubinstein and Drevet have been fully considered but they are not persuasive.

Applicant argues that one would not have modified Rubenstein with flexible diaphragm. This argument has not been found persuasive because both the piston arrangement and the flexible diaphragm of Drevet were well known means for adjusting the height of a flow control piston - specifically, fluid pressure presses on the surface thereof to change the height of the piston. It would have been completely within the scope of one of ordinary skill in the art to use a flexible diaphragm at the bottom portion of the piston instead of Rubenstein's L-shaped piston arrangement.

Further, applicant's statement that a diaphragm does not necessarily have a linear response is simply false. Drevet uses this exact system to impart linear motion on his piston.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Philip R. Wiest whose telephone number is (571)272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Philip R Wiest/
Examiner, Art Unit 3761

/Leslie R. Deak/
Primary Examiner, Art Unit 3761
30 September 2010